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| 09/974,781  | 10/10/2001  | Michael G. Kahn      | FSTK 1004-1         | 8124               |
| 22470   | 7590        | 12/18/2006           | EXAMINER            |                    |
| HAYNES BEFFEL & WOLFELD LLP<br>P O BOX 366<br>HALF MOON BAY, CA 94019 |             |                      |                     | COBANOGLU, DILEK B |
| ART UNIT  |             | PAPER NUMBER         |                     |                    |
|   |             | 3626                 |                     |                    |

DATE MAILED: 12/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                          |                                       |                         |  |
|--------------------------|---------------------------------------|-------------------------|--|
| <b>Interview Summary</b> | <b>Application No.</b>                | <b>Applicant(s)</b>     |  |
|                          | 09/974,781                            | KAHN ET AL.             |  |
|                          | <b>Examiner</b><br>Dilek B. Cobanoglu | <b>Art Unit</b><br>3626 |  |

All participants (applicant, applicant's representative, PTO personnel):

- (1) Dilek B. Cobanoglu. (3) Warren wolfeld (Reg. No. 31,454).  
 (2) Rachel Porter (Senior Examiner A.U. 3626). (4) \_\_\_\_\_.

Date of Interview: 05 December 2006.

Type: a) Telephonic b) Video Conference  
 c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 1,10 and 42.

Identification of prior art discussed: Brown (6,196,970), Herren (6,108,635).

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiners and Applicant's Representative discussed about relative language used in claims 1, 10 and 42 causing 112 rejection.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

## Summary of Record of Interview Requirements

### **Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### **Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or-not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



**ATTACHMENT TO  
APPLICANT INITIATED INTERVIEW REQUEST FORM  
OF December 4, 2006**

Application No. 09/974,781, Filed October 10, 2001  
Michael G. Kahn, et. al.  
Group Art Unit: 3626  
Examiner: Dilek B. Cobanoglu

**Brief Description of Arguments to be Presented**

Basically two types of rejections remain: claim indefiniteness (vagueness) and unpatentability over prior art.

**INDEFINITENESS (Claims 1, 10 and 42)**

The indefiniteness rejections all seem to turn on the phrase in these claims calling for the step of, while encoding protocol workflow tasks into a database, identifying an operational uncertainty in which "said protocol specification specifies such a parameter too vaguely to be encoded into said database." The Examiner's position appears to be that since the claim does not state any limitations on "said database", this claim language is unclear. Applicants' position is that the claim calls for encoding workflow tasks into "a database", so by the time the step of identifying an operational uncertainty is to be performed, "a database" has already been identified, and that is the database against which vagueness of the parameter is to be measured. There is nothing indefinite about identifying an operational uncertainty in which a protocol specification specifies a parameter too vaguely to be encoded into a particular, identified database.

As explained in MPEP 2173.02, the definiteness requirement of 35 USC 112 is satisfied when the claim meets "threshold requirements of clarity and precision." Other useful excerpts from MPEP 2173.02:

- "[T]he examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent....

- [T]he totality of all the limitations of the claim and their interaction with each other must be considered...."

Thus the definiteness inquiry sensibly depends on whether one of ordinary skill can determine from the claim language whether or not they infringe. And the entire claim must be considered, not just the single excerpt that the Examiner appears to be focused on.

The Examiner is invited to consider how an infringement analysis would proceed. Infringement (as used herein, Applicants refer only to direct literal infringement) requires a reading of every limitation of the claim against the accused product or method. Referring to claim 1, the person would first determine whether the accused method performs a step of "encoding into a database, workflow tasks called for in a clinical trial protocol specification ...."

If the accused method does not perform even one limitation of this step, then there is no direct literal infringement and the inquiry ends. **Thus it is not possible to get past this step without having a particular database in mind**, into which the accused method encodes workflow tasks called for in a clinical trial protocol specification. This has to be a *real* database, into which the accused method *really* encodes workflow tasks. If the person does not have a particular database in mind, then this first claim step is not satisfied, and there is no infringement.

Only if the person gets past this first step, meaning that the person has a particular *real* database in mind as satisfying the first claim step, do they go on to the next step, which is to determine whether the accused method performs a step of, "during said step of encoding workflow tasks ..., identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter too vaguely to be encoded into said database, or said protocol specification specifies such a parameter inconsistently."

There is nothing unclear to the person making the infringement analysis, about which database is being referred to in the phrase "said database": the word "said" linguistically has only one antecedent basis in the claim, which is the database referred to in the first claim step. And if the person is considering whether the accused method satisfies the second step, then the person already has in mind a *particular database* as being "said database". (Of course the person making

the infringement analysis could try working backwards, considering whether the second claim step is satisfied before considering the first claim step, but the person would quickly see the need to first identify a particular "said database" used by the accused method, that satisfies the limitations of the first claim step.)

**So the Examiner's position** that claim 1 is unclear because the claim does not state any limitations on "said database", **does not address the legal test for determining whether the claim is sufficiently definite to satisfy Section 112**. The test (as set forth in the MPEP excerpts above) is whether a person of ordinary skill can determine from the claim language whether or not they infringe. And when a person makes that analysis regarding the claimed step of identifying an operational uncertainty in which ... "said protocol specification specifies such a parameter too vaguely to be encoded into said database", they will be comparing this claim language to a particular database that they have already identified as being "said database".

Either this database exists or it does not exist. No other circumstances are possible. If it does not exist then the accused method fails the first claim limitation, and does not infringe for that reason. If it does exist then that database is the database to be examined to determine whether the protocol specification "specifies a parameter too vaguely to be encoded into" that database.

The Examiner's assertion that the particular database is not *described in the claim*, is simply not relevant to the definiteness analysis. A person of ordinary skill would have no trouble determining whether a particular accused method infringes the claims because in order to satisfy the first limitation of the claim a particular database already has to have been identified. And the ability of a person to be able to make this determination is all that matters to make claim 1 definite.

The same discussion above also applies to the Section 112 rejection of claims 10 and 42.

#### **OBVIOUSNESS (All claims)**

It appears from the Advisory Action that the prior art rejections continue to depend on the Examiner's extraordinarily broad interpretation of the term, "operational uncertainty". The

Examiner takes the position that when the term is read that broadly, the claimed invention is obvious over a combination of Brown and Friedman.

**But in reading the Advisory Action, Applicants wonder whether the Examiner simply forgot about the points raised and claim amendments that Applicants made in Response A.**

In Response A, Applicants pointed to a definition of the term "operational uncertainty" in the specification, and even inserted the definition (roughly) directly into the claim language.

In the next Office Action the Examiner simply repeated her rejections, but added an additional reference to the prior art combination (Herren). No explanation was given why Response A was insufficient.

Applicants pointed this out in Response B, and argued further that Herren takes place before a protocol is drafted (contrary to claim limitations calling for an existing protocol), and that Herren concerned scientific uncertainties rather than "operational" uncertainties. Applicants also argued that the Examiner is ignoring the specific definition language that had been inserted into the claim.

But in the advisory action, the Examiner says:

Applicant argues that Herren reference does not teach operational uncertainty, protocol specification fails to specify a particular parameter for use during protocol execution. At the March 2, 2006 interview, Examiners suggested that the method claim 1 and the rest of the claims would be amended to clarify the meaning of "operational uncertainty". With the broadest interpretation, Examiner respectfully submits that the combination of references ... teach these limitations as explained in the previous office action.

This paragraph completely ignores that Applicants (in Response A) *did* respond to the Examiners' suggestion in the March 2, 2006 interview, by amending to clarify the meaning of "operational uncertainty", just as suggested. It is just as if the Examiner had forgotten that Applicants' Response A already did this.

**Before bringing this case to the Board of Appeal, therefore, Applicants wonder whether the Examiner simply forgot about the points raised and claim amendments made in Response A, when she issued her Advisory Action.**

If the Examiner did not forget about Response A, and really does still believe that the term "operational uncertainty" is to be read so broadly (in its "broadest reasonable

interpretation") as to render Applicants' obvious over a combination of Brown, Friedman and Herren, then Applicants respectfully point out that the phrase "broadest reasonable interpretation" does not give the Examiner license to ignore the usage in the specification. The principle of applying the broadest reasonable interpretation is not purely a matter of Examiner's discretion, as "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach" in light of the specification. MPEP 2111, (citing *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999), in which the Federal Circuit reversed the Board's construction of a claim limitation based on applicant's disclosure and other published examples of usage). It is important to tie the meaning of "operational uncertainty" to how the term would be understood by those of skill in the art in light of the specification.

As Applicants pointed out in Response A, specification paragraph [0104] (for example) gives meaning to the phrase "operational uncertainty":

[0104] As used herein, "operational uncertainties" include parameters that are either specified inconsistently in the text-based protocol, or specified only vaguely, or omitted altogether. Some parameters in a clinical trial protocol are left uncertain intentionally, and a well-designed database model will accommodate this level of uncertainty. For example, the temporal constraint from one protocol event to another may be specified in the text-based protocol as a permissible range of time periods, or as minimum, maximum and base time periods, or as a probability function. These may constitute "operational uncertainties" with respect to a simple database model that requires entry of only a single precise time period, but not with respect to more sophisticated database models that allow entry of the temporal constraint parameters in the form provided in the text. As another example, protocol specifications that intentionally allow some discretion on the part of the physician, are not necessarily "operational uncertainties". Thus an uncertainty is not considered an "operational uncertainty" unless the protocol specifies the parameter either with unintentional ambiguity, or not at all, or with sufficient unintentional uncertainty that it cannot be encoded into the database without additional information from the provider of the protocol.

This specification language cannot be ignored when giving the claim phrase "operational uncertainty" its broadest reasonable interpretation.

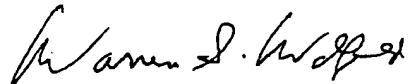
Furthermore, even if the term "operational uncertainty" is given no patentable weight at all, Applicants' Response A incorporated limitations directly into the claim calling for identifying an uncertainty of any of three specified types. Nothing in Brown teaches or suggests identifying

an uncertainty of any of the three types specified in Applicants' claim. Certainly nothing in Brown or Herren teaches or suggests identifying such an uncertainty in the protocol specification.

\* \* \* \* \*

The Examiner is thanked for the courtesy of this interview and hopes that it will be productive.

Respectfully submitted,



Warren S. Wolfeld  
Reg. No. 31,454

Haynes Beffel & Wolfeld LLP  
P.O. Box 366  
Half Moon Bay, CA 94019  
(650) 712-0340 phone  
(650) 712-0263 fax